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P.O. Box 503 Antigo, WI 54409-0503

> Telephone (715) 623-2301 1-800-356-5655 FAX: (715) 623-4501

Web Site: WWW.newnorth.net/antigo.cheese

May 25, 2000

Ms. Felicia Satchell
Chief Foods Standards Branch
Food & Drug Administration
Office of Food and Labeling (HSS-158)
Center for Food Safety and Applied Nutrition
200 C. Street SW
Washington DC 20204

Dear Ms. Satchell:

The purpose of this letter, pursuant to the provisions of 21CFR Section 130.17, is to request a temporary permit to produce and test market Parmesan Cheese produced by the make procedure described in the Parmesan Standard, 21CFR para. 133.165, with the exception that we propose to age the cheese for six-months instead of the standard ten months.

In order to achieve the texture, taste and functional characteristics of a cheese that has aged for ten months we add an additional safe and suitable enzyme (which has been recognized as safe for use in foods including cheese). Attached is a copy of our proprietary make procedure for Parmesan cheese which is aged for six months.

The reasons we are applying for this temporary permit to market six months old Parmesan cheese are as follows:

- 1. Our customers are requesting a six-month Parmesan to meet competitive situations.
- 2. Six-month Parmesan is as nutritionally equivalent and safe as a ten month Parmesan.
- Curing and holding periods required to produce a ten month Parmesan are quite expensive. A six month cheese enables us to reduce our costs which in turn will reduce the costs to the consumer. We find and our tests confirm that the organoleptic properties

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of our six-month Parmesan are equivalent to our ten month Parmesan. Internal and external sensory evaluation and external nutritional analysis confirm that the nutritional equivalency of the two products are comparable. This test data is included with this application.

As required by 21CFR para. 130.17 we are submitting the following information for a temporary permit to produce and market Parmesan cheese aged for six-months which is identical in all aspects to the standard of identity for Parmesan cheese of ten months with the exception of the 4-months aging difference.

Upon your review, we request a TMP take effect upon date of issuance.

Upon the successful completion of our tests, we will propose the aged standard for Parmesan Cheese be reduced from ten months to six-months.

Thank you for your consideration of this request and application. Please call me at 715-623-2301 if you require any additional information.

Sincerely,

Leo Malone

Sales/Marketing Manager

Enclosures

- 1) Applications pursuant to 21CFR paragraph 130.17
- 2) Parmesan Make Procedure
- 3) Proposed Label
- 4) Research and Tests Results

Name of Address of Applicant

The Antigo Cheese Company

907 9th Avenue

P.O. Box 503

Antigo, Wisconsin 54409-0503

Statement Regarding Applicant Producing the Product

Antigo Cheese has produced and sold Parmesan Cheese to the retail, food service and ingredient distribution chains since 1993.

References to Applicable Standards of Identity

The Antigo Cheese Company requests temporary permit to produce and sell Parmesan Cheese which has been aged for six-months rather than the traditional ten months.

Description of the Proposed Variation

The Parmesan Cheese we propose will be identical in all regards to standard Parmesan cheese except for the reduced storing time from ten months to six-months. Characteristics including texture, flavor and color will remain the same. Moisture will be at 32% maximum, minimum milk fat content of 32%, as determined by the method described in Section 133.5 (A)(B) and (D). Our make procedure for this proposed product is attached as Exhibit A.

Basis for Belief that the Food is Wholesome

The wholesomeness, flavor, texture and nutritional characteristics of the six-month aged

Parmesan we propose will be equivalent to our current ten month Parmesan cheese. No unique or
novel ingredients or processes are involved in the production of this product. The additional
enzyme used has been recognized as GRAS by FDA and has a long history of usage in cheese
manufacture.

External sensory evaluation indicates the proposed Parmesan is organoleptically equivalent to our current ten month Parmesan cheese. (See Exhibit B)

Nutritional equivalency analysis was conducted by a reputable, independent laboratory, MVTL Laboratories, New Ulm Minnesota. The results show the proposed six month Parmesan to be nutritionally equivalent on DRV or RDI values to the current ten month Parmesan (See Exhibit C). The proposed six month Parmesan complies with the current standard of identity for Parmesan, with exception to the ten month aging requirement.

The Amount of Any New Ingredient and Deviation from the Standard

The only deviation is the use of another enzyme which is commonly used in the cheese industry and has history of safe and suitable use with the advantage of a shorter curing period. No other new ingredients are proposed.

Purpose for the Variation from the Standard

- 1) Response to customer requests.
- 2) To meet anticipated competitive situations, domestic and potential future threats regarding imported cheese with standards different from our own.
- 3) To take advantage of new enzymes and aging techniques.
- 4) To eventually petition amending the current standard of identity regarding the 10-month aging requirement.

Variations Advantage to the Consumer

Lower production, aging and inventory costs which may be passed on to the consumer. Lower costs will enable small manufacturers, like Antigo Cheese, to be more competitive and thereby stimulate competition in the market place.

Test Timetable

The Antigo Cheese requests the tests of six-month aged Parmesan for a period of 15 months upon approval of the request. This 15-month period will enable Antigo to evaluate our results within a similar time table granted to other applicants with this same type of cheese.

Probable Amount of Six-Month Parmesan to be Distributed

Up to 20 million pounds.

Areas of Distribution

We propose the	six-month Parn	nesan will be dis	tributed and sold th	roughout the Ur	ited States.

Manufacturing Address

The proposed product will be produced at The Antigo Cheese Company, 907 9th Avenue, Antigo, Wisconsin, 54409.

Distribution in the State of Manufacture

The Parmesan Cheese we propose will be distributed in the state of Wisconsin.

Why-Not Distributed in a State of Manufacturer

Not applicable. As noted above product will be distributed in the State of Wisconsin where we propose to manufacture.

Reasons for Distribution in to Several States

Our customer base includes major marketers who sell our product nationally. They have requested this product and it would be impossible to limit the marketing of this proposed Parmesan to small geographic areas. This proposed test will allow our customers to test the product nationally and remain competitive in the marketplace.

EXHIBIT B

Results of external sensory evaluation showing the proposed six month Parmesan is statistically equivalent to ten month parmesan.

EXHIBIT C

Results of nutritional equivalency testing showing the proposed six month Parmesan is nutritionally equivalent to ten month Parmesan.



MINNESOTA VA

1126 N. Front St. - New Uli 1411 S. 12th St. - Bismarck, 710 S. 14th St. - Grand Fork 35 W. Lincoln Way - Nevade

LABORATORIES, INC.

557 - Fax 507-359-2890 5 - Fax 701-258-9724 45 - Fax 701-772-0028 5 - Fax 515-382-3885



Report Date: 24 Apr 2000

Lab Number: 00-M10000 Work Order #: 3782 Account Number: 001068

Date Sampled: Time Sampled:

Date Received: 6 Apr 2000

MATT DOCHTERMAN
THE ANTIGO CHEESE COMPANY
907 9TH AVE
ANTIGO WI 54409-0503

Sample Description: 10 MONTH PARMESAN CHEESE

NUTRITIONAL INFORMATION PER 100 grams

Analyte	Result		
	===============		
Moisture	30.53	g	
Ash	5.81	g	
Calories	403.61	Kcal	
Calories from Fat	261.1	Kcal	
Total Fat	29.01	g	
Fat, Saturated	18.42	g	
Cholesterol	77.0	mg	
Sodium	1016	mg	
Total Carbohydrate Content	< 0.01	g	
Sugars	< 0.2	g	
Protein - Kjel N x 6.38	35.63	g	
Vitamin A	1782.8	IU	
Vitamin C	5.1	mg	
Calcium	1046	mg	
Iron	0.268	mg	

Approved by:

Michael K. Grob, Laboratory Manager

Original Results
April 200



. - New Ulm, MN 56073 - 800-782-3557 - Fax 507-359-2890 - Bismarck, ND 58502 - 800-279-6885 - Fax 701-258-9724 Grand Forks, ND 58201 - 800-272-7645 - Fax 701-772-0028 ay - Nevada, IA 50201 - 800-362-0855 - Fax 515-382-3885



Report Date: 24 Apr 2000

Lab Number: 00-M9999 Work Order #: 3782 Account Number: 001068

Date Sampled: Time Sampled:

Date Received: 6 Apr 2000

MATT DOCHTERMAN THE ANTIGO CHEESE COMPANY 907 9TH AVE ANTIGO WI 54409-0503

Sample Description: 6 MONTH PARMESAN CHEESE ENZYME ADDED

NUTRITIONAL INFORMATION PER 100 grams

Analyte	Result	
	=======	==========
Moisture	30.65	g
Ash	5.53	g
Calories	396.98	Kcal
Calories from Fat	255.1	Kcal
Total Fat	28.34	g
Fat, Saturated	18.18	g ·
Cholesterol	76.3	mg
Sodium	915.0	mg
Total Carbohydrate Content	1.33	g
Sugars	< 0.2	g
Protein - Kjel N x 6.38	34.15	g
Vitamin A	1184.4	IU
Vitamin C	4.1	mg
Calcium	972.0	mg
Iron	< 0.247	mg

Michael K. Grob, Laboratory Manager

Original Reals
April 2000